UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,381	03/15/2004	Iddys D. Figueroa	200401494-1	3173

7590 12/19/2006

HEWLETT-PACKARD COMPANY
Intellectual Property Administration
P. O. Box 272400
Fort Collins, CO 80527-2400

EXAMINER	
CAMERON, ERMA C	
ART UNIT	**PAPER NUMBER**
1762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,381	FIGUEROA ET AL.	
	Examiner	Art Unit	
	Erma Cameron	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 29-34* is/are pending in the application.

4a) Of the above claim(s) *34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Election/Restrictions

1. Claim 34 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 34 now requires identifying a desired surface-to-mass ratio and applying dots to achieve the desired surface-to-mass ratio, whereas the originally-filed claims and those embodied now in the invention of claims 1-10 and 29-33 are directed to a process of identifying a desired dissolution rate and applying dots to achieve the desired dissolution rate. While claim 34 did previously outline a process of controlling dissolution rates by applying dots to achieve a desired surface-to-mass ratio, the achievement was argued by Examiner to be inherent and there were previously no claimed active method step of selecting a desired surface-to-mass ratio. These inventions now embody independent and distinct method limitations.

The applicant has argued in the 10/5/2006 amendment that achieving a desired surface-to-mass ratio is an intermediate attribute of positioning drops of solution, and therefore claim 34 is subject matter that is not independent and distinct. The examiner disagrees for the reasons given above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claim 34 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

2. The terminal disclaimers to 10/801379 and 10/801380 have been received and approved.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 6-8, 29-30, and 32-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Voss et al. (4,322,449).

Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern (abstract; throughout; col. 5, lines 35-37).

Voss teaches the control of various parameters, such as dots/second, volume/drop, number of ejection strokes, etc. As is known in the art and as taught in the specification, controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently provide control over the dissolution rate. The precise nature of Voss' printing technique yields such control.

As for the limitation of first "identifying a target dissolution rate", Examiner notes that safe and effective administration of a drug (bioactive agent) to a patient requires a precise dose at an acceptable "target" dissolution rate. Medical professionals, such as doctors, pharmacists, and pharmaceutical company scientists, are of ordinary skill in this art. Medical personnel would have been aware that a too-rapid dissolution rate could lead to an over-dose, whereas a too-slow dissolution rate could lead to ineffective treatment levels. Neither of these risks is acceptable. Also, many medications are provided in a controlled release (CR) form to provide the correct dose over a period of time, inherently requiring the use of a target dissolution rate. Therefore, when creating a drug delivery substrate, it is Examiner's position that it would have been inherent for one of ordinary skill in the art to identify, in addition to a desired target dose, a target dissolution rate. The patterns of dots placed down on the delivery substrate of Voss would have been inherently placed to achieve said target dissolution rate for the safety and health of medical patients.

In the alternative, for all the reasons stated above, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to select a target dissolution rate to be achieved by the patterns of Voss to ensure the safe and effective administration of drugs to patients.

One of ordinary skill in the art would have been well aware of the effects of surface area on dissolution rate, for example, that a plurality of small thin dots would dissolve faster than a thick, large dot. As evidence of this awareness, as outlined above, Voss teaches control of the parameters that would be known by ordinary artisans in the medical coating art to impact dissolution rate.

Voss teaches the use of a piezoelectric ejection element (abstract) with a number of nozzles (col. 4, line 18).

Voss provides the bioactive agent in a solvent (col. 5, lines 52-62), which inherently dries by evaporation, with precisely controlled concentration and drop volume (col. 6, line 5).

Voss refers to some dots as being discrete, with a specified volume. Dots are "spaced". Voss also uses his method to write letters (Ex. 2), requiring, in some instances, at least a partial overlap of dots.

Regarding claim 3, requiring sufficient spacing to avoid coalescing, Voss' method of creating spaced, discrete dots sufficiently spaces the dots.

Claim 29 is added to this rejection for the same reasons that Voss is applied to claim 1. Voss' control over various parameters will inherently achieve the dissolution rate.

Claim 30 is rejected for the same reasons as claim 2.

Claim 32 is rejected for the same reasons as claim 3.

Regarding claim 33, the substrate of Voss is ingestible (see Examples).

Claim Rejections - 35 USC § 103

8. Claims 9-10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss.

Voss teaches that which is disclosed above, but fails to specifically teach the standard deviation regarding the spacing or overlapping of droplets. However, Voss goes to great lengths

to discuss the precision, uniformity, and reproducibility of the dot sizes, dosages, and concentrations he applies. Because a plate of nozzles may be used in a fixed arrangement, the dots formed should always be spaced the same, i.e., with a deviation approaching zero percent. It would have been obvious to an ordinary artisan wishing to achieve uniformity and precision in dosing to select and maintain a spacing that is consistent from dot to dot, i.e., with a standard deviation of less than 15%.

While achieving perfect uniformity is impossible, Voss' teachings clearly direct one of ordinary skill in the art to precisely space the dots with *no standard deviation*, i.e., with a deviation approaching 0%, which would be less than 15%. Voss creates dosage zones on his ingestible substrate with specific dosage ratios. Incorrect spacing would yield a zone with too many or too few dosage dots, leading to dosage error. Likewise, in creating letters, another embodiment of Voss, a uniform spacing of the dots which create the letters would be necessary to yield letters with smooth lines (letters made of dots with varying spacing would be thicker in some areas).

It is well settled that determination of optimum values of cause effective variables such as standard deviation is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 31, it is Examiner's position that in the creation of letters or other desired geometric patterns, Voss will desirably select a second dot to fully overlap a first dot to create a larger dot in a given location. It would have been within the skill of an ordinary artisan

to "fully" overlap one dot with another if a larger "ink" spot is needed to create a letter, such as in, for example, dotting an "i".

9. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss, as applied above, in view of Voges (5,894,841).

Voss teaches that which is disclosed above, namely forming droplets of bioactive agent using piezoelectric ejection elements. What Voss does not teach is the use of thermal ejection elements.

It is Examiner's position that these two species of inkjet printing are obvious variants that would have been known to an ordinary artisan and cites Voges for teaching the same.

Voges teaches a method of forming droplets of bioactive agent by using one of the two forms of inkjet printing, namely either a piezoelectric ejection device or a thermal ejection device.

Since Voss teaches printing precise drops of bioactive agent using a piezoelectric element, such as is used in inkjet printing, and Voges teaches that either the piezoelectric or thermal types of inkjet printing are suitable for forming precise droplets of bioactive agent, Voges would have reasonably suggested the use of a thermal element in the method of Voss. It would have been obvious to one of ordinary skill in the art to use the interchangeability teachings of Voges in the method of Voss to provide Voss with a suitable, successful alternative element for dosing dots in a precise manner.

Like Voss, Voges teaches a plurality of nozzles or ejection orifices that provide uniformly-sized droplets.

Response to Arguments

10. Applicant argues that Voss does not identify a target dissolution rate or position drops based on the target dissolution rate.

Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern. A desired pattern of dots indicates a decision was made to select a specific pattern and location of all dots, the first, second, and subsequent ones. The precise dosing of the active substance, with precise control over volume, spacing and concentration will have the effect of controlling the dissolution rate of the active substance, and these parameters are therefore selected with this control in mind.

The safe and effective administration of drugs requires correct quantities (i.e., dose) at correct rates of administration (i.e., dissolution rates). Any pattern selected in the use of the Voss reference must be selected based on dose and rate. A delivery substrate pattern yielding the incorrect dose and/or dose rate would be unacceptable. One of ordinary skill in the art must have these two factors in mind when creating a pattern of drug dots and when testing the delivery substrate. Even if the dose and dose rate are only tested in R&D after manufacture (but before sale), using a trial-and-error method, one of ordinary skill in the art must still have a desired target dose/dissolution rate in mind, i.e., one that was "identified". In fact, Applicant's own

specification states that "a desired dissolution rate can be discovered through experimentation, in which one or more application parameters are varied until a desired dissolution rate is achieved" and that drop size, nozzle size, solution concentration, drying temperatures, and drop pattern are all appropriate parameters to vary (p. 20). These parameters would have all been well-known by one of ordinary skill in the medical coating and administering art to impact the rate at which a coating would dissolve from a substrate.

Further Voss teaches the control of these various parameters, such as dots/second, volume/drop, number of ejection strokes, etc. Examiner maintains that controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently and/or obviously provide control over the dissolution rate. The precise nature of Voss' printing technique yields such control, which is imperative to safe dosing of bioactive agents. When dosing a patient, a physician inherently considers the amount of therapeutic agent in addition to the rate at which the dose is administered.

The applicant has further argued that Voss does not position dots at selected locations based on the target dissolution rate. The examiner would point to Voss's printing of dots in the form of letters (Example 2) as an example of controlling dot spacing, and inherently therefore dissolution rate.

Conclusion

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Erma Cameron

ERMA CAMERON
PRIMARY EXAMINER

Erma Cameron
Primary Examiner
Art Unit 1762

December 18, 2006